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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,631	06/21/1999	JOHN MICHAEL MANNERS	CULLN23.001A	1902

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/331,631

Applicant(s)
Manners et al.

Examiner
HOPE ROBINSON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11-21, 30, 31, 34, 36, 37, and 39-54 is/are pending in the application.
- 4a) Of the above, claim(s) 12, 14, 15, 34, 36, 37, 39, and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 13, 16-21, 30, 31, and 41-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's response to the Office Action mailed July 16, 2002 in Paper No. 18 on January 23, 2003 is acknowledged.

Claim Disposition

2. Claims 32 and 33 have been canceled. Claims 46-54 have been added. Claims 3, 11, 13, 16, 17, 18, 30, 34, 43, 44 and 45 have been amended. Claims 1-3, 11-21, 30, 31, 34, 36, 37, 39-54 are pending. Claims 1-3, 11, 13, 16-21, 30, 31 and 41-54 are under examination.
3. The following grounds of rejection are or remain applicable :

Specification

4. The specification remains objected to as failing to provide proper antecedent basis for the claimed subject matter (See 37 CFR 1.75(d)(1) and MPEP § 608.01(o)). Correction of the following is required: the added material which is not supported by the original disclosure is as follows: claim 1 has been amended to read that "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue". It is noted that applicant in Paper

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No.18 amended the specification to provide support for the claims, however, this is regarded as new matter.

Cancellation of the new matter in the claims and the specification is required.

5. The amendments filed September 17, 2001 remains objected to under 35 U.S.C. 132 because the amendment introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 1 has been amended to read that "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue". It is noted that the amendment filed January 23, 2003 amends the specification to provide support, however, this amendment also introduces new matter.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 1-3, 11, 13, 16-21, 30, 31 and 41-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is directed to a purified or isolated protein fragment having antimicrobial activity and methods of controlling microbial infestation. Claim 1 and the dependent claims hereto introduced new matter into the claims because it is recited that "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue". The amendment filed January 23, 2003 amends the specification to provide support, however, this amendment also introduces new matter into the claims. In addition, the claimed invention has not been adequately described as claim 16 requires a search of databases using an "unspecified/unknown algorithm" to identify an amino acid sequence in the claimed method and there is no indicia as to what sequence, what algorithm, what database is to be employed to identify this sequence. Does any sequence apply to applicant's method? The claims broadly recite that the protein has antimicrobial activity, however, note that example 15 (Table 1) lists 15 organisms and only 5 organism exhibited 50% inhibition of growth with the composition used (see page 29 of the specification). This demonstrates antimicrobial activity to some extent, however, does not provide sufficient guidance as to a method to control microbial infestation. Note also that the specification on page 29 supports this conclusion by stating that there was a reduction observed but not an elimination.

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Thus, it is apparent that the specification lacks sufficient guidance/written description for one of skill in the art to be able to practice the claimed invention without performing undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2, 11, 13, 16-18, 20-21, 41-42, 46, 48, 50-51 and 53 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 11, 13 and 17-21 still lack antecedent basis for the phrase "X is any amino acid other than cysteine" as the specification does not provide support for this phrase.

Claim 13 remains indefinite because the claim is a method claim which improperly depends from a product claim.

Claim 16 remains indefinite because of the recitation of "an unspecified/unknown algorithm to be used to identify or design an amino acid sequence" as the metes and bounds of the method is not defined.

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Claim 46 is indefinite for the recitation of "composition comprising". The claim should be amended to recite "A composition comprising".

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claim 1 remains rejected under 35 U.S.C. 102 (a) as being anticipated by Tatar et.al. (EP 093652, November 9, 1996).

Tatar disclose peptides used to vaccinate against *E. coli* enterotoxins. In addition, Tatar disclose the sequence contained in SEQ ID No: 39 with the formula C3XC12XC3XC wherein X is any amino acid and C is cysteine, with a 100% sequence identity. Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

9. Claim 1 remains rejected under 35 U.S.C. 102 (a) as being anticipated by Voerman (WO 96/13585, May 9, 1996).

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Voerman disclose protease inhibitors obtainable from leeches. Voerman also disclose a medicament and pharmaceutical preparations. Voerman further disclose the sequence contained in SEQ ID No: 37 with a 100% sequence identity where the sequence is C3XC10XC3XC, wherein X is any amino acid and C is cysteine (see the alignment and abstract). Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

10. Applicant's arguments filed on January 23, 2003 in Paper No. 18 have been fully considered but were not persuasive. Note that the rejections under 35 U.S.C. 112, first and second paragraph and 102(a) remains. *In addition, new grounds of rejections have been added for the reasons stated above. Regarding the rejection under 35 U.S.C. 112, first paragraph with respect to the issue of new matter presented in the amendment filed September 17, 2001, "applicant contends that they do not deny that there is an absence of such an explicit recitation in the description, however, the disclosure as a whole must be considered. The response further states that Ex parte Parks allows for the requirement of the first paragraph to be satisfied if the originally filed disclosure would have conveyed to one having ordinary skill in the art that applicants had possession of the claimed subject matter even if a particular concept was not literally stated in the originally filed application". This argument is not persuasive because applicant is essentially asking one skilled in the art to insert information that is not written in the disclosure in to provide support for the claims. The statement made on page 9 of the response is

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very clear “[A]pplicants do not deny that there is an absence of such an explicit recitation in the description”. How then can absence of information be interpreted as applicants had possession of the claimed subject matter. It is noted that applicant has instructed the PTO to amend the specification to provide support for the terminology recited in claim 1 on pages 4 and 10, however, this amendment also introduces new matter. Applicant also contends that as the claimed invention is directed to cysteine spacing “X is any amino acid other than cysteine”. However, this is not accurate, for example, “X” is any amino acid” can produce the following result: “C-2X-C-3X-C....” can be equivalent to “C-A-C-DDD-C” or “C-AA-DDD-C...” etc. The proviso that “X” is any amino acid, does not mean that every appearance of “X” has a “cysteine” residue. Also note that claims such as 44 still recite the proviso “X is any amino acid residue”. What is disclosed or recited is what is considered during examination and any amendments to that lack support is new matter. Applicant is directed to see *In re Johnson* and *Ex parte Grasselli*. Hence the maintenance of the objections to the specification and rejections under 35 U.S.C. 112, first paragraph and 102(a). With regard to the rejection under 35 U.S.C. 102(a) the references remains applicable since applicant did not cancel the new matter material (as addressed on pages 16-17 of the response). The instant response referred to the Declaration submitted under 37 CFR 1.132 which was considered in Paper No.16. As stated in the previous office action the Declaration is not persuasive because the recitation of the negative limitation inserted into the claim by the amendment is new matter as the phrase “X is any amino acid other than cysteine” is not supported by the instant specification and to amend the specification to include this limitation

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is also new matter. Therefore, the claim can be interpreted in the way that the art has been applied.

Regarding the rejection under 35 U.S.C. 112, second paragraph, note that the rejection of remains applicant's arguments were not persuasive. It is stated in the response that "item (a) of claim 13 depends from claim 1 which applicant regards as a compound, not a product as asserted by the Examiner". Claim 1 is directed to an isolated or purified protein fragment, which makes the claim a product claim. It is suggested that applicant recited the limitations of claim 1 in the method claim and remove the dependency to claim 1. As the new matter in claim 1 has not been canceled the ground of rejection over claim 1 and the dependent claims thereto remains for the reasons stated above. The rejection remains over claim 16 as the amendments made did not further clarify the claim. Unknown components remain in the method step, thus, the metes and bounds of the claim has not been defined. Note that the newly submitted claims have also been rejected under this statute for the reasons stated above. Thus the rejection remains.

Conclusion

11. No claims are allowable.
12. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

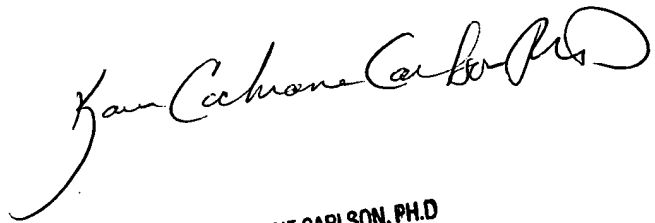
Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

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Hope A. Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER